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FRANK M. FLOWER & SONS INC.

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GROWERS OF PINE ISLAND OYSTERS

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July 6, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Re: (Docket No. 99N-1075)

Answers to "Questions to be Considered by the Risk Assessment"

1. A pathogenic strain of *Vibrio parahaemolyticus* (Vp) was assumed to be present in the waters of Oyster Bay Harbor for the first time in August of 1999. The organism (strain 03:K6) was found in patient stool samples but never in shellfish or water samples. Eight cases of gastroenteritis were reported between 8/10 and 8/29. No illnesses were reported after 8/29 even though shellfish were harvested and sold through 9/10. This indicates that the time period that the toxic Vp was supposedly present was only 19 days. Water temperature during that time was about 80 degrees F or 5 degrees above normal.

2. Since no cases of Vp illness have ever been reported from Oyster Bay before, we think that it is a rare occurrence. If not for a *Vibrio cholera* alert from New York City the small number of Vp cases would not have been noticed. Toxic *Vibrio* could not be found in any shellfish samples from Oyster Bay. That being the case, it would probably be impossible to find it in water samples.

3. Questions no.3 are beyond the scope of the shellfish farming industry. They must be answered by the scientists and health people.

4. There is good potential that poor post harvest handling of shellfish could cause elevated Vp numbers. We feel that this should not be a problem at Frank M. Flower and Sons Inc. however since we closely follow HACCP guidelines. It is well known that refrigeration can limit and even kill Vp cells. Unfortunately depuration and relaying are not as effective with Vp as they are with typical sewage related pathogens. The time frame is considerably longer. If closures are long term however, relaying may still be a viable option.


5. There is currently considerable knowledge of Vp in Asia. In the U.S. Vp became a problem only recently. (Washington State 1997). Effort should be focused on sampling of shellfish and collecting environmental data so that background Vp levels and Vp requirements can be assessed. Infective levels must be determined in order to effectuate timely closures. Criteria for reopening affected areas must be clear cut. Oyster Bay stayed closed for 6 weeks after the problem was gone in 1998. The current Interim Control Plan for Vp must be revised to address the 03:K6 strain.

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All of the shellfish that were supposedly associated with Vp illness in New York in 1998 came from a 20 acre area. Shellfish were harvested only 2 miles from the suspect area during the entire closure and did not cause illness. The New York situation was so small that it can practically be considered a non-event.

Sincerely:

A handwritten signature in black ink, appearing to read "David R. Relyea". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

David R. Relyea  
CO OWNER

FRANK M. FLOWER & SONS, INC.

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OYSTER BAY, NY 11771-0088

DOCKET NO. 99N-1075

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